510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 7, 2013

Submitter: GE Healthcare
9900 Innovation Drive
Wauwatosa, WI, USA 53226

SEP 24 2013

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare
Phone: (414) 721-4214
Fax: (414) 918-8275

Secondary Contact Person: Charlotte Kaas Munthe Jørgensen
Regulatory Affairs Specialist
GE Healthcare, GE Vingmed Ultrasound AS
Phone: +47 33 02 12 80
Fax: +47 33 02 13 50

Device: Trade Name: GE EchoPAC

Common/Usual Name: Workstation Software for ultrasound image review, analysis and reporting

Classification Names: 21 CFR 892.2050

Product Code: LLZ

Predicate Device(s): K123894 - GE EchoPAC

Device Description: GE EchoPAC provides image processing, annotation, analysis, measurement, report generation, communication, storage and retrieval of ultrasound images that are acquired via GE Vivid family of ultrasound scanners, primarily for cardiology ultrasound applications but also for general imaging. The EchoPAC software is an integral component of each Vivid system, providing the post-acquisition image management and reporting functions of the scanner. EchoPAC will be offered as SW-only to be installed directly on customer PC hardware, or as an accessory to selected 3rd party image management workstations. EchoPAC is DICOM

compliant, transferring images and data via LAN between scanners, hard copy devices, file servers and other workstations. The modified or added software features for GE EchoPAC are substantially equivalent to the predicate device and functionality cleared on GE EchoPAC K123894.

Intended Use:

The GE EchoPAC workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Clinical applications include: Fetal; Abdominal (including renal and GYN); Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

The device may include EchoPilot reporting software which provides guidance to support the quality of the echocardiography examination and report. It compares patient data, user entered clinical data and measurements to generally accepted guidelines and studies, and helps to identify mismatches, inconsistencies and unusual or missing data. It can generate a preliminary data analysis that can be used as basis for the examination report.

Device Modification Overview:

The following is a brief overview of the differences between the proposed EchoPAC and the predicate EchoPAC (K123894).

The following modifications of existing features available on the predicate EchoPAC will be introduced with the modified EchoPAC:

1. 4D Strain: Export of 4D strain trace and mesh data.
2. 2D Strain: - Multilayered 2D strain
   - Variable width ROI
   - Add Caliper
3. Alternative automated ROI tracing for Auto EF and AFI features
4. Depth Illumination map

The subject modified EchoPAC will introduce one new plug-in feature originally cleared in its own right by their OEM

manufacturer, Sony Electronics.

5. Polarized Stereo Vision, visualization of 3D data on Sony LMD-2451MT LCD monitor, K113203, intended for 3D and 2D color video displays of clinical images.

The Intended Use and Indications for Use of the device have not changed by this modification.

These modifications all lead to ease of use of the EchoPAC

Technology: The EchoPAC employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates, including conformance to DICOM standard.

Summary of Clinical Tests:

The subject of this premarket submission, EchoPAC, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the EchoPAC to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

GE VINGMED ULTRASOUND AS
% Mr. Bryan Behn
Regulatory Affairs Manager
GE HealthCare
9900 Innovation Drive, RP-2138
WAUWATOSA WI 53226

Re: K131685
Trade/Device Name: Ge EchoPAC
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 22, 2013
Received: August 23, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

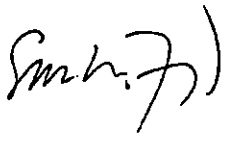
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number: K131685

Device Name: GE EchoPAC

Indications for Use:

The GE EchoPAC workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Clinical applications include: Fetal; Abdominal (including renal and GYN); Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

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Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: NO (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131685